New Cholesterol Treatment Guidelines

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Objectives:
• List the 4 treatment groups under the new guidelines
• Identify how to calculate the risk score for primary prevention
• Recognize that high potency statins are the preferred treatment
• Relate that the guidelines do not ignore people under 40 and over 75
• Indicate that you actually measure lipids every 3 to 12 months after you put people on a statin
New Cholesterol Treatment Guidelines--2013

NHBLI, American Heart Association, American College of Cardiology Guidelines

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Diplomat American Board of Lipidology

Based on presentation by Jeffrey L Anderson, MD
Chair of ACC/AHA Task Force on Practice Guidelines.
2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Preventive Cardiology, Association of Black Cardiologists, Preventive Cardiovascular Nurses Association, and WomenHeart: The National Coalition for Women with Heart Disease
IN GOD WE TRUST,
OF ALL OTHERS WE REQUIRE DATA
Citation

This slide set is adapted from the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults. E-Published on November 12, 2013, available at:

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.
Guideline Scope

• Focus on *treatment of blood cholesterol to reduce ASCVD risk in adults*

• Emphasize adherence to a heart healthy lifestyle
  - See Lifestyle Management Guideline

• Identify individuals *most likely to benefit from cholesterol-lowering therapy*
  - 4 statin benefit benefit groups

• Identify safety issues
New Perspective on LDL–C & Non-HDL–C Goals

• Lack of RCT evidence to support titration of drug therapy to specific LDL–c and/or non-HDL–c goals
• Strong evidence that *appropriate intensity of statin therapy* should be used to reduce ASCVD risk *in those most likely to benefit*
• Quantitative comparison of statin benefits with statin risk
• Nonstatin therapies – did not provide ASCVD risk reduction benefits or safety profiles comparable to statin therapy
Why Not Continue to Treat to Target?

Major difficulties:

1. Current RCT data do not indicate what the target should be
2. Unknown magnitude of additional ASCVD risk reduction with one target compared to another
3. Unknown rate of additional adverse effects from multidrug therapy used to achieve a specific goal
4. Therefore, unknown net benefit from treat-to-target approach
4 Statin Benefit Groups

ASCVD Statin Benefit Groups
Heart healthy lifestyle habits are the foundation of ASCVD prevention. In individuals not receiving cholesterol-lowering drug therapy, recalculate estimated 10-y ASCVD risk every 4-6 y in individuals aged 40-75 y without clinical ASCVD or diabetes and with LDL–C 70-189 mg/dL.

Adults age >21 y and a candidate for statin therapy

Clinical ASCVD

Yes

Age ≤75 y
High-intensity statin
(Moderate-intensity statin if not candidate for high-intensity statin)

IA

No

Yes

Age >75 y OR if not candidate for high-intensity statin
Moderate-intensity statin

IA

LDL–C ≥190 mg/dL

Yes

High-intensity statin
(Moderate-intensity statin if not candidate for high-intensity statin)

IB

No

Yes

Moderate-intensity statin

IA

Diabetes
Type 1 or 2
Age 40-75 y

Yes

High-intensity statin
Estimated 10-y ASCVD risk ≥7.5%*

IlaB

No

No
4 Statin Benefit Groups (con’t)

Estimate 10-y ASCVD Risk with Pooled Cohort Equations*

≥7.5% estimated 10-y ASCVD risk and age 40-75 y

Yes

Moderate-to-high intensity statin

No

ASCVD prevention benefit of statin therapy may be less clear in other groups

In selected individuals, consider additional factors influencing ASCVD risk‡ and potential ASCVD risk benefits and adverse effects, drug-drug interactions, and patient preferences for statin treatment

*10-year ASCVD Risk Calculator online
<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Units</th>
<th>Value</th>
<th>Acceptable range of values</th>
<th>Optimal values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>M (for males) or F (for females)</td>
<td>F</td>
<td>M or F</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>years</td>
<td>59</td>
<td>20-79</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>AA (for African Americans) or WH (for whites or others)</td>
<td>AA</td>
<td>AA or WH</td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>mg/dL</td>
<td>180</td>
<td>130-220</td>
<td>170</td>
</tr>
<tr>
<td>HDL-Cholesterol</td>
<td>mg/dL</td>
<td>40</td>
<td>20-100</td>
<td>50</td>
</tr>
<tr>
<td>Systolic Blood Pressure</td>
<td>mm Hg</td>
<td>140</td>
<td>90-200</td>
<td>110</td>
</tr>
<tr>
<td>Treatment for High Blood Pressure</td>
<td>Y (for yes) or N (for no)</td>
<td>Y</td>
<td>Y or N</td>
<td>N</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Y (for yes) or N (for no)</td>
<td>N</td>
<td>Y or N</td>
<td>N</td>
</tr>
<tr>
<td>Smoker</td>
<td>Y (for yes) or N (for no)</td>
<td>N</td>
<td>Y or N</td>
<td>N</td>
</tr>
</tbody>
</table>

**Your 10-Year ASCVD Risk (%)**

9.3

**10-Year ASCVD Risk (%) for Someone Your Age with Optimal Risk Factor Levels (shown above in column E)**

2.7

**Your Lifetime ASCVD Risk* (%)**

39.6

**Lifetime ASCVD Risk (%) for Someone at Age 50 with Optimal Risk Factor Levels (shown above in column E)**

6.0

*This is the lifetime ASCVD risk for an individual at age 50 years with your risk factor levels. In rare cases, 10-year risks may exceed lifetime risks given that the estimates come from different approaches. While 10-year risk estimates are derived from methods and data using a 10-year look-ahead approach, lifetime risk estimates are derived from methods and data using a 50-year look-ahead approach.*
## Intensity of Statin Therapy

### Table 5. High- Moderate- and Low-Intensity Statin Therapy (Used in the RCTs reviewed by the Expert Panel)*

<table>
<thead>
<tr>
<th>High-Intensity Statin Therapy</th>
<th>Moderate-Intensity Statin Therapy</th>
<th>Low-Intensity Statin Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily dose lowers LDL–C on average, by approximately ≥50%</td>
<td>Daily dose lowers LDL–C on average, by approximately 30% to &lt;50%</td>
<td>Daily dose lowers LDL–C on average, by &lt;30%</td>
</tr>
<tr>
<td><strong>Atorvastatin (40†)–80 mg</strong></td>
<td><strong>Atorvastatin 10 (20) mg</strong></td>
<td><strong>Simvastatin 10 mg</strong></td>
</tr>
<tr>
<td><strong>Rosuvastatin 20 (40) mg</strong></td>
<td><strong>Rosuvastatin (5) 10 mg</strong></td>
<td><strong>Pravastatin 10–20 mg</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Simvastatin 20–40 mg‡</strong></td>
<td><strong>Lovastatin 20 mg</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Pravastatin 40 (80) mg</strong></td>
<td><strong>Fluvastatin 20–40 mg</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Lovastatin 40 mg</strong></td>
<td><strong>Fluvastatin XL 80 mg</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Fluvastatin 40 mg bid</strong></td>
<td><strong>Pitavastatin 1 mg</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Pitavastatin 2–4 mg</strong></td>
<td></td>
</tr>
</tbody>
</table>

*Individual responses to statin therapy varied in the RCTs and should be expected to vary in clinical practice. There might be a biologic basis for a less-than-average response.
†Evidence from 1 RCT only: down-titration if unable to tolerate atorvastatin 80 mg in IDEAL (Pedersen et al).
‡Although simvastatin 80 mg was evaluated in RCTs, initiation of simvastatin 80 mg or titration to 80 mg is not recommended by the FDA due to the increased risk of myopathy, including rhabdomyolysis.
Clinical ASCVD

Initiating Statin Therapy

Clinical ASCVD
Not currently on statin therapy
Initial evaluation prior to statin initiation
- Fasting lipid panel*
- ALT
- CK (if indicated)
- Consider evaluation for other secondary causes (Table 6) or conditions that may influence statin safety (Table 8, Rec 1).

Evaluate and Treat Laboratory Abnormalities
1. Triglycerides ≥500 mg/dL
2. LDL–C ≥190 mg/dL
   - Secondary causes (Table 6)
   - If primary, screen family for FH
3. Unexplained ALT >3X ULN

Aged ≤75 y without contraindications, conditions or drug-drug interactions influencing statin safety, or a history of statin intolerance
- Initiate high-intensity statin therapy
  - Counsel on healthy lifestyle habits

Aged >75 y† OR with conditions or drug-drug interactions influencing statin safety, or a history of statin intolerance
- Initiate moderate-intensity statin therapy
  - Counsel on healthy lifestyle habits

Monitor statin therapy (Figure 5)
Primary Prevention

*Initiating Statin Therapy*

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**No Clinical ASCVD**

- Not currently on cholesterol-lowering drugs
- Initial evaluation prior to statin initiation
  - Fasting lipid panel
  - ALT
  - Hemoglobin A1c (if diabetes status unknown)
  - CK (if indicated)
  - Consider evaluation for other secondary causes (Table 6) or conditions that may influence statin safety (Table 8, Rec 1)

---

**Evaluate and Treat Laboratory Abnormalities**

1. Triglycerides ≥500 mg/dL
2. LDL-C ≥190 mg/dL
   - Secondary causes (Table 6)
   - If primary, screen family for FH
3. Unexplained ALT >3X ULN

---

**Assign to statin benefit group**

(Figure 2)

*Counsel on healthy lifestyle habits*

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**Diabetes and age 40-75 y†**

- OR
- LDL-C ≥190 mg/dL

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**No diabetes, age 40-75 y, and LDL-C 70-189 mg/dL**

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**Helping Cardiovascular Professionals**


[American Heart Association logo]
Primary Prevention

Initiating Statin Therapy (con’t)

1. Estimate 10-y ASCVD risk† with Pooled Cohort Equations
   - Yes
     - ≥7.5% 10-y ASCVD risk
     - 5%-<7.5% 10-y ASCVD risk
   - <5% 10-y ASCVD risk
   - Age <40 or >75 y and LDL−C <190 mg/dL

2. Clinicians and patients should engage in a discussion of the potential for:
   - ASCVD risk reduction benefits§
   - Adverse effects§
   - Drug-drug interactions
   - Patient preferences

3. Initiate statin therapy (Figure 2)
   - Re-emphasize healthy lifestyle habits

4. Monitor statin therapy (Figure 5)

In selected individuals, additional factors may be considered to inform treatment decision making‡
Primary Prevention
Global Risk Assessment

• To estimate 10-year ASCVD risk
  ▪ New Pooled Cohort Risk Equations
  ▪ White and black men and women

• More accurately identifies higher risk individuals for statin therapy
  ▪ Focuses statin therapy on those most likely to benefit
  ▪ You may wish to avoid initiating statin therapy in high-risk groups found not to benefit (higher grades of heart failure and hemodialysis)
Primary Prevention
Statin Therapy

• Thresholds for initiating statin therapy derived from RCTs
• Before initiating statin therapy, clinicians and patients engage in a discussion of the potential for ASCVD risk reduction benefits, potential for adverse effects, drug-drug interactions, and patient preferences
Individuals Not in a Statin Benefit Group

- In those not clearly in a statin benefit group, additional factors may inform treatment decision-making:
  - *Family history of premature ASCVD*
  - *Elevated lifetime risk of ASCVD*
  - *LDL-c ≥160 mg/dL*
  - *hs-CRP ≥2.0 mg/L*
  - *Subclinical atherosclerosis*
    - CAC score ≥300 or ABI<0.9
    - *Very low HDL*

- Discussion of potential for ASCVD risk reduction benefit, potential for adverse effects, drug-drug interactions, and patient preferences
Safety

- RCTs & meta-analyses of RCTs used to identify important safety considerations
- Allow estimation of **net benefit** from statin therapy
  - ASCVD risk reduction versus adverse effects
- Expert guidance on management of statin-associated adverse effects, including muscle symptoms
- Advise use of additional information including pharmacists, manufacturers prescribing information, & drug information centers for complex cases
Statin Therapy: Monitoring Response and Adherence

Assess medication and lifestyle adherence
Fasting lipid panel

Anticipated therapeutic response?

Yes

Reinforce continued adherence
Follow-up 3-12 mo

No

Less-than-anticipated therapeutic response

Intolerance to recommended dose of statin therapy?

Yes

Management of statin intolerance
(Table 8, Rec 8)

No

Anticipated therapeutic response?

Yes

No

Indicators of anticipated therapeutic response and adherence to selected statin intensity:
- High-intensity statin therapy reduces LDL-C approx. ≥50% from the untreated baseline.
- Moderate-intensity statin therapy reduces LDL-C approx. 30% to <50% from the untreated baseline.
‡In those already on a statin, in whom baseline LDL–C is unknown, an LDL–C <100 mg/dL was observed in most individuals receiving high-intensity statin therapy in RCTs.
Vignettes: Putting a face on patients in whom ASCVD risk reduction works

- 63 yo man with STEMI, discharged on a high-intensity statin
- 26 yo woman with elevated LDL–c of 220 mg/dL, noted in teens + family history CHD
- 44 yo woman with diabetes, well-controlled hypertension and micro-albuminuria
- 56 yo African-American man with multiple ASCVD risk factors
Case 1: ASCVD ≤75 years of age

- 63 yo man STEMI
- Non Smoker
- Chol 150 mg/dL, HDL-c 25 mg/dL, TG 150 mg/dL
- Non HDL 125 mg/dL, LDL-c 95 mg/dL
Lessons From the Vignettes

None of these need ASCVD risk calculation:

• Case 1: ASCVD ≤75 years of age
  o Evidence supports high-intensity statin therapy for optimal risk reduction in those who tolerate it
  o Moderate intensity may be initiated or used if >75 yo
  o Also, if high-intensity Rx not safe or not tolerated

• Case 2: LDL–C ≥190 mg/dL; other causes ruled out
  o Evidence supports high-intensity statin therapy
  o LDL–C levels may still remain very high, even after the intensity of statin therapy has been achieved; addition of a nonstatin drug may be considered to further lower LDL–c
Case 2: LDL–C ≥190 mg/dL

• 26 yo woman with elevated LDL–c of 220 mg/dL, noted in teens + family history CHD

• Newly married
  – Wants to bear children
  – Wants to adopt and not bear children
Lessons From the Vignettes

None of these need ASCVD risk calculation:

- **Case 1: ASCVD ≤75 years of age**
  - Evidence supports high-intensity statin therapy for optimal risk reduction in those who tolerate it
  - Moderate intensity may be initiated or used if >75 yo
  - Also, if high-intensity Rx not safe or not tolerated

- **Case 2: LDL–c ≥190 mg/dL; other causes ruled out**
  - Evidence supports high-intensity statin therapy
  - LDL–C levels may still remain very high, even after the intensity of statin therapy has been achieved; addition of a nonstatin drug may be considered to further lower LDL–c
Case 3: Diabetes; 40-75 yo

- 44 yo woman with diabetes, well-controlled hypertension and micro-albuminuria
- Non smoker, chol 180 mg/dL, HDL-c 40 mg/dL
- 2.8% 10-year risk
- 50% lifetime risk
Lessons From the Vignettes

ASCVD risk calculator useful in these:

• Case 3: Diabetes; 40-75 yo; LDL–c 70-189 mg/dL
  - Evidence supports moderate-intensity statin Rx to be initiated or continued
  - High-intensity statin Rx reasonable if estimated 10-year ASCVD risk calculated to be >7.5%

• Case 4: Primary prevention; not low risk for ASCVD
  - Use Pooled Cohort Equations (risk calculator) to estimate 10-year ASCVD risk for individuals with LDL–C 70 to 189 mg/dL to guide initiation of statin therapy
  - Engage in a treatment discussion with patient before treatment is initiated
Case 4: Primary prevention; not low risk for ASCVD

- 56 yo African-American man with multiple ASCVD risk factors
- Smoker
- No DM
- Systolic BP 160 mmHg (No Rx)
- Positive FH
- Chol 200 mg/dL, HDL-c 45 mg/dL
- 10-year risk 17.6%, Lifetime risk 69%
Lessons From the Vignettes

ASCVD risk calculator useful in these:

• Case 3: Diabetes; 40-75 yo; LDL–c 70-189 mg/dL
  - Evidence supports moderate-intensity statin Rx to be initiated or continued
  - High-intensity statin Rx reasonable if estimated 10-year ASCVD risk calculated to be >7.5%

• Case 4: Primary prevention; not low risk for ASCVD
  - Use Pooled Cohort Equations (risk calculator) to estimate 10-year ASCVD risk for individuals with LDL–c 70 to 189 mg/dL to guide initiation of statin therapy
  - Engage in a treatment discussion with patient before treatment is initiated
SUBJECT: Recent ACC/AHA lipid lowering guidelines.

Charles F. Dahl, MD

(Full text: Circulation November 12, 2013)

This communication is meant to give a very brief overview of the recently released lipid-lowering guidelines. This will attempt to simply hit the highlights. The guidelines appear to be somewhat complicated and may be misunderstood when they are first seen. However, with familiarity, they become logical. They are based on the best evidence available. The writing committee relied heavily on randomized clinical trials.

There are four groups in whom statin therapy is considered:

1. Individuals with ASCVD.
   Primary Prevention (groups 2, 3, and 4).
2. Individuals with familial hypercholesterolemia (either homozygous or heterozygous; LDL cholesterol ≥190).
3. Individuals with diabetes ages 40 to 75.
   a. Diabetics with a risk score ≥7.5.
   b. Diabetics with a risk score <7.5.
4. Individuals not fitting in groups 1, 2, or 3 who are ages ≥40 and ≤75.
   a. Risk score ≥7.5.
   b. Risk score ≥5.0 and < 7.5.

The use of high potency statins (atorvastatin 40 or 80 g; rosuvastatin 20 or 40 mg) are recommended for group 1 (known ASCVD), group 2 (individuals with familial hypercholesterolemia), and group 3a (diabetics with a risk score ≥7.5). The reason that high potency statins in high doses are recommended is due to randomized clinical trials showing benefit in these patients using these agents in these doses.

Group 3b (diabetics with a risk score ≤ 7.5) and group 4a (individuals aged 40 to 75 with risk scores ≥ 7.5) are to receive moderate to high dose statin depending
on patient and physician preference and other potential risk modifying factors (see below). Moderate dose statins include doses of atorvastatin 20 mg or less, rosuvastatin 10 mg or less, and other statins such as simvastatin, pravastatin, etc.

The risk calculator can be easily downloaded to a cell phone or computer. The app is ASCVD Risk Estimator. The risk score includes male or female sex, age, race, total cholesterol, HDL cholesterol, systolic blood pressure, treatment for hypertension, diabetes status, and smoking status. This risk calculator gives both a 10-year and lifetime risk. The risks of 7.5 and 5.0 referred to above is the 10-year risk.

The guidelines are quite explicit in recommending that these are, in fact, guidelines and do not replace clinical judgment. In addition to the calculated risk score, careful consideration of other aspects of a patient’s other potential risk modifying characteristics, including family history, calcium score, CRP extremely low HDL, lifetime risk, and LDL cholesterol >160 should all be taken into consideration. However, they are not given specific quantification.

It appears by casual perusal of the guidelines that once a person is on a high potency or moderate potency statin, his lipids need not be checked again. In fact, the guidelines recommend checking lipids every 3-12 months. One would want to check lipids at least annually to help ensure compliance and to give the patient the message that continued use of statins is very important. In addition, periodic assessment of lipids may cause one to evaluate the patient for changing clinical status that would lead to investigation of new disease states or other conditions which could affect the lipid levels.

Of note, the only clearly recommended drugs for risk reduction are statins. The only other clear recommendations relate to lifestyle modifications. Non-statin lipid-modifying agents can be used if the physician and patient wish to, for example, attempt to achieve lipid levels as seen in the old guidelines. However, there is currently a lack of clear convincing evidence for reduction of events with agents such as ezetimibe, niacin, fibrates, and fish oils. Again, clinical judgment and patient and physician preferences are stressed.
The guidelines do not ignore people under 40 or over 75. They do emphasize that clinical judgment is to be used in these people. Of note, a risk score can be calculated from age 20 to age 79. In addition, factors such as family history, CRP, etc., should be considered in all individuals. For example, if a 36-year-old with an HDL of 21 with a father who had a heart attack at age 42 were presented, it would make sense to offer that patient a high potency statin.

Hopefully this will shed some light on the recommendations.
Some Thoughts About Guidelines

- Use of RCTs is good
- Emphasize statins (especially high potency, high dose)
- Stroke prevention
- Expand use of statins (maybe too much)
- May give sometime erroneous impression that you should back off or not use statins for age > 75 or < 40
Some Thoughts About Guidelines Continued

- Non use of target cholesterol levels (controversial to say the least.
- Risk equation maybe too inclusive for statin use in 60-70s
- Lack of mention if LDL-Particles and HDL-Particles
- Cut off of data after 2009
- Emphasis “These are guidelines and do not replace clinical judgment”
HDL-C/HDL-Particles
• HDL-c is clearly a potent risk factor
• HDL-p is a more potent risk factor
• AIM HIGH study and Heart Protection II study both showed no benefit of adding niacin to patients on statins (with well controlled LDL-c).

• Clear benefit has been shown in many RCTs using generally high potency statins (presumably by lowering LDL-c, non HDL-c and LDL-p)
• Therefore when using drug therapy in patients with low HDL, use statins to attempt to lower LDL-c, non HDL-c and LDL-p to improve total chol/HDL-c ratio.
• Encourage lifestyle modifications (weight loss, smoking cessation, exercise) to raise HDL-c.
PCS K9

BLOCKBUSTER or SIDESHOW

It depends on whether their success brings back LDL targets
SUBJECT: RECENT ACC/AHA LIPID LOWERING GUIDELINES.

Charles F. Dahl, MD

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